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UNITED STATES
HOUSE OF REPRESENTATIVES
ROSA L. DELAURO
3RD DISTRICT, CONNECTICUT

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November 9, 2017

The Honorable Pete Sessions
Chairman
The Committee on Rules
United States House of Representatives
Washington, D.C. 20515

The Honorable Louise M. Slaughter
Ranking Member
The Committee on Rules
United States House of Representatives
Washington, D.C. 20515

Dear Chairman Sessions and Ranking Member Slaughter,

I write to urge you to oppose any provision into the conference agreement of the 2018 National Defense Authorization Act (NDAA) that would unilaterally grant the Department of Defense (DOD) the authority to approve drugs and medical devices for emergency use. While crafted with good intentions, this action is likely to undermine the objective of the Food and Drug Administration (FDA) and potentially give rise to serious unintended consequences.

Currently, the FDA is the only agency with the authority to authorize medical drugs and devices for emergency use. In some cases, unapproved medical products that have not been proven safe and effective through a thorough evaluation conducted by the FDA turn out to be harmful – even if they initially seemed promising. As an agency, the FDA collects and maintains critical information regarding the safety and efficacy of unapproved medical products. While the Senate provision states DOD must consult with FDA, the section does not guarantee that the entirety of FDA's expertise and scientific information will even influence the DOD's final decision.

Presently, the FDA has means of allowing for emergency access to unapproved medical products that focus on protecting individuals who undergo their treatment. These authorizations include Investigational New Drug (IND) process as well as expanded access IND mechanisms. These mechanisms ensure access to treatment while also maintaining certain protections like informed consent and institutional reviews.

This potentially irresponsible change in regulatory authority could unnecessarily expose American soldiers to increased risk and potential harm. Unapproved medical products generally have not been shown to be effective in their experimental use, and even worse have not been shown to be safe. We have a responsibility to ensure that troops injured in combat are treated

safely and effectively, not subject to medical experiments on the battlefield. I urge you to strike this provision in the rule for the bill.

Thank you for your attention to this pressing matter and I look forward to your prompt response.

Sincerely,

Rosa L. DeLauro
Member of Congress